

**IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF TENNESSEE
WESTERN DIVISION**

FREDDIE JONES, LUKE JONES, TRENNNA JONES,
RALPH JONES, LAVON JONES, and JIMMY FREEMAN,
as Surviving Children of ELNORA JONES,

Plaintiffs,

v.

CIVIL ACTION
CASE NO. 07-02120-WGY

ABBOTT LABORATORIES,

Defendant.

ORDER OF CERTIFICATION

I. INTRODUCTION

Freddie Jones, Luke Jones, Trenna Jones, Ralph Jones, Lavon Jones, and Jimmy Freeman (collectively, the "Joneses") brought a products liability action against Abbott Laboratories ("Abbott") to recover damages allegedly caused by Humira, a drug that Abbott manufactures. Elnora Jones ("Jones"), the Joneses' deceased mother, took Humira to treat her rheumatoid arthritis. The Joneses' tort claims chiefly accuse Abbott of failing to warn about the risk of lymphoma associated with taking Humira. Abbott moved for summary judgment, invoking the learned intermediary doctrine (the "doctrine") as a defense to the Joneses' claims. The doctrine states that drug manufacturers discharge their duty to warn of prescription drugs' risks by cautioning the physician who, in her capacity as learned intermediary, conveys the warning

to the patient. Pittman v. Upjohn Co., 890 S.W.2d 425, 429 (Tenn. 1994). Following Pittman v. Upjohn Co., 890 S.W.2d 425, this Court ruled that Tennessee law recognizes the doctrine in deciding Abbott's summary judgment motion. The Tennessee Supreme Court has not, however, addressed whether the doctrine applies to a prescription drug manufacturer that pays physicians to prescribe its drug or advertises its products directly to consumers -- both of which are allegations that the Joneses make against Abbott. Given the changed medical landscape since 1994, when the Tennessee Supreme Court last held that the learned intermediary doctrine governs a prescription drug company's duty to warn, this Court's ruling presents issues of first impression.

II. PRIOR PROCEEDINGS

Jones commenced this action against Abbott on February 15, 2007, in the Western District of Tennessee. Compl., ECF No. 1. Abbott gave notice of Jones's death on September 6, 2007. Suggestion Death, ECF No. 16. Jones's counsel subsequently moved to substitute parties for Jones. Pl.'s Mot. Substitution Fed. R. Civ. P. 25(a)(1) & Req. Hr'g, ECF No. 18. Abbott responded to this motion, Resp. Def. Abbott Pl.'s Mot. Substitution, ECF No. 21, and moved to dismiss, Def.'s Mot. Dismiss Compl., ECF No. 22. Jones's counsel also moved to amend the complaint to include the substituted parties. Pl.'s Mot. Leave File Am. Compl., ECF No. 25. At a motion hearing on February 20, 2008, the Court granted

the motions to substitute parties for Jones and to amend the complaint. Elec. Clerk's Notes, Feb. 20, 2008, ECF No. 36. The Court also denied Abbott's motion to dismiss, since its sole ground for dismissal was that the motion to substitute parties, which the Court granted, should not be permitted. Order Dismissing Moot Def. Abbott's Mot. Dismiss, ECF No. 40. The Joneses, Jones's surviving children, were substituted as plaintiffs in an amended complaint. Second Am. Compl.¹, ECF No. 38. They asserted strict liability, negligence, implied warranty, consumer protection, and wrongful death claims against Abbott. Id. Abbott answered the amended complaint on March 28, 2008. Ans. Second [Sic] Am. Compl., ECF No. 42.

After taking discovery, Abbott filed a motion for summary judgment, Def. Abbott's Mot. Summ. J. ("Mot. Summ. J."), ECF No. 190, along with its statement of undisputed facts, Mot. Summ. J., Attach. 2, Def. Abbott's Statement Undisputed Material Facts Supp. Its Mot. Summ. J., ECF No. 190-2, and a supporting memorandum, Mot. Summ. J., Attach. 1, Def. Abbott's Mem. P. & A. Supp. Its Mot. Summ. J., ECF No. 190-1.

Pursuant to the Court's Visiting Judge Program, I received this case on July 9, 2012. Elec. Clerk's Notes, July 9, 2012, ECF No. 191. On July 27, 2012, the Joneses filed a motion to

¹ Despite its title, this document is the Jones's first amended complaint.

certify questions of state law to the Tennessee Supreme Court. Pls.' Mot. Certify Questions State Law Tenn. Supreme Ct. ("Mot. Certify"), ECF No. 193. In addition, they responded to Abbott's summary judgment motion. Pls.' Resp. Def.'s Mot. Summ. J. ("Pls.' Resp."), ECF No. 194; Pls.' Resp., Attach. 1, Pls.' Br. Opp'n Def.'s Mot. Summ. J., ECF No. 194-1; Pls.' Statement Undisputed Material Facts, ECF No. 196; Pls.' Resp. Def.'s Statement Undisputed Material Facts ("Pls.' Resp. Facts"), ECF No. 195. Abbott opposed the Joneses' motion to certify questions of state law, Def. Abbott's Opp'n Pls.' Mot. Certify Questions State Law Tenn. Supreme Ct. ("Opp'n Mot. Certify"), ECF No. 200, and the Joneses submitted a reply brief, Pls.' Reply Mem. Supp. Mot. Certify Questions State Law Tenn. Supreme Ct. ("Reply Mot. Certify"), ECF No. 204. Abbott responded to the Joneses' memorandum opposing summary judgment, Def. Abbott's Reply Supp. Mot. Summ. J., ECF No. 197, and to their undisputed fact statement, Def. Abbott's Resp. Pls.' Statement Undisputed Material Facts ("Def. Resp. Pls.' Facts"), ECF No. 198.

Oral argument on Abbott's summary judgment motion and the Joneses' certification motion occurred on September 28, 2012. Elec. Clerk's Notes, Sept. 28, 2012, ECF No. 207. This Court denied in part and granted in part Abbott's summary judgment motion, denying summary judgment on the negligence, implied warranty, and strict liability for failure to warn claims due to

genuine issues of disputed material facts. Id. Because the Tennessee Supreme Court's decision in Pittman is controlling, in deciding Abbott's summary judgment motion, this Court ruled that the learned intermediary doctrine governs Abbott's duty to warn. Mot. Hr'g Tr. 26:19-20, ECF No. 208. Nevertheless, allegations regarding Abbott's payments to Jones's prescribing physician and the Humira advertising campaign targeting consumers raise issues of first impression as to the scope of the learned intermediary doctrine. See Pls.' Resp. Facts; Def. Resp. Pls.' Facts.

Consequently, this Court granted the Joneses' motion to certify state law questions to the Tennessee Supreme Court because the scope of the doctrine may very well be outcome determinative in this case. Elec. Clerk's Notes, Sept. 28, 2012, ECF No. 207. The parties have since filed a joint case management proposal, WGY Am. Scheduling Order, ECF No. 210, and this case is on track for trial.

III. BACKGROUND

Abbott manufactures Humira, a prescription drug that is used to treat moderately to severely active rheumatoid arthritis. Pls.' Resp. Facts ¶ 1. Dr. R. Franklin Adams ("Dr. Adams") prescribed Humira to Jones in November 2004 to treat her "severe" rheumatoid arthritis. Id. ¶¶ 50, 61. Jones was diagnosed with lymphoma in 2006. Id. ¶ 64. The Joneses argue that Abbott is

liable in tort for its failure to warn of the risk of lymphoma associated with taking Humira. See Pls.' Resp. 3.

Because the Joneses' allegations involve a failure-to-warn theory of liability, the duty to warn that Tennessee law imposes on prescription drug manufacturers is central to this case. In Pittman, the Tennessee Supreme Court adopted the learned intermediary doctrine, deciding that prescription drug companies' duty to warn runs to physicians, or learned intermediaries, who transmit the warnings to patients. See 890 S.W.2d at 429. In dicta, in a failure-to-warn case involving a manufacturer of asbestos-containing insulation, the Tennessee Supreme Court recently reaffirmed the doctrine's applicability to prescription drug manufacturers' duty to warn. See Nye v. Bayer Cropscience, Inc., 347 S.W.3d 686, 689-90, 701, 703 (Tenn. 2011) ("Physicians, who play a pivotal role in the distribution of prescription drugs, are the intermediaries relied on by manufacturers to give warnings to patients." Id. at 701). But the court has not applied the doctrine to a prescription drug manufacturer itself since its 1994 decision in Pittman, nor has it considered the doctrine's relevance to prescription drug cases where manufacturers' "direct-to-consumer" advertisements or payments to physicians are at issue.

In this case, the Joneses allege that Abbott's "significant" compensation to Jones's rheumatologist, Dr. Adams, for his

participation in a purported clinical study facilitated a crude program in which Abbott paid Dr. Adams for each patient to whom he prescribed Humira. See Pls.' Resp. Facts ¶ 32. Further, they allege that Abbott conducted a comprehensive marketing campaign for Humira across various media that targeted patients and did not adequately disclose the risk of lymphoma. See Pls.' Statement Undisputed Material Facts ¶¶ 4, 5, 7. Thus, the Joneses and Abbott dispute the doctrine's application in cases where a prescription drug manufacturer advertises directly to consumers or pays physicians who prescribe its drug(s).

A. The Parties' Proposed Constructions

1. Petitioner's² Construction

Petitioner argues that "sea changes" in the medical industry since Pittman was decided in 1994 undermine the rationale supporting application of the doctrine to prescription drug manufacturers. Mot. Certify 14. Namely, pharmaceutical companies' paying physicians to prescribe their drugs undercuts the physicians' ability to serve as the objective or learned intermediaries that center in the doctrine. Id. at 9-11. Also, the proliferation of targeted consumer advertising of

² Because the Joneses moved to certify state law questions to the Tennessee Supreme Court, see Mot. Certify, this Court designates the Joneses as the moving party and petitioner, see Tenn. Sup. Ct. R. 23(6) ("The party designated by the certifying court as the moving party shall be referred to as the petitioner and the party adverse to the petitioner shall be referred to as the respondent.").

prescription drugs changes the "backdrop for the traditional doctor/patient relationship," id. at 9, such that prescription drugs are no longer "marketed solely to professionals," id. at 3 (quoting Pittman, 890 S.W.2d at 430) (internal quotation marks omitted), as was the case when Pittman was decided. Rather, pharmaceutical companies' "nontraditional[] and intentional[] marketing efforts" circumvent the traditional doctor-patient relationship. Reply Mot. Certify 3. Thus, Petitioner argues that the Tennessee Supreme Court would likely recognize exceptions to the doctrine in cases where prescription drug companies advertise directly to consumers or pay physicians for prescribing their drugs. Mot. Certify 14, 17. Alternatively, Petitioner suggests that the Tennessee Supreme Court may adopt section 6(d)(2) of the Restatement (Third) of Torts: Products Liability in reaction to the changed healthcare environment. Id. at 14. The Restatement recognizes that physicians are not always well positioned to fulfill their role as learned intermediaries. See Restatement (Third) of Torts: Prods. Liab. § 6(d)(2) (1998).

It states:

A prescription drug . . . is not reasonably safe due to inadequate . . . warnings if reasonable instructions or warnings regarding foreseeable risks of harm are not provided to . . . the patient when the manufacturer knows or has reason to know that health-care providers will not be in a position to reduce the risks of harm in accordance with the instructions or warnings.

Id.

2. Respondent's³ Construction

Respondent argues that the Tennessee Supreme Court's decisions in Pittman and Nye v. Bayer Cropscience, Inc., 347 S.W.3d 686, suggest that the court is not inclined to recognize any exceptions to the doctrine. Opp'n Mot. Certify 1, 2-4. When the Tennessee Supreme Court first applied the doctrine in a failure-to-warn case involving prescription drugs, it emphasized the physician's role as gatekeeper in the distribution of those drugs. See id. at 3 ("Physicians are [learned] intermediaries because of the pivotal role they play in the unique system used to distribute prescription drugs" (alteration in original) (quoting Pittman, 890 S.W.2d at 429) (internal quotation marks omitted)). Because neither consumer ads nor physician compensation from pharmaceutical companies abrogate the physician's "pivotal role in the distribution of prescription drugs," id. at 4 (quoting Nye, 347 S.W.3d at 701) (internal quotation mark omitted), respondent argues that the rationale for applying the doctrine to prescription drug cases in Pittman remains relevant today, see id. at 3-4.

IV. THIS COURT'S CONSTRUCTION

In deciding Abbott's summary judgment motion, this Court ruled that the doctrine governs Abbott's duty to warn about

³ This Court designates Abbott as the respondent. See Tenn. Sup. Ct. R. 23(6).

Humira's risks. Mot. Hr'g Tr. 26:19-20. Thus, Abbott discharged its duty to warn under Tennessee law if it communicated the relevant risks to Jones's prescribing physician.

This Court refused to recognize an exception to the doctrine in this case. It reasoned that consumer ads do not eliminate the importance of physicians' expert and individualized medical judgment -- or their role as learned intermediaries -- when deciding to prescribe an injection-administered biologic drug, such as Humira. See Nye, 347 S.W.3d at 703 ("Prescription drugs are likely to be complex medicines, esoteric in formula and varied in effect. As a medical expert, the prescribing physician can take into account the propensities of the drug as well as the susceptibilities of his patient."). Also, rather than automatically abrogate the learned intermediary doctrine in cases where physicians receive payments from drug manufacturers, fact finders can assess physicians' credibility and impartiality when applying the doctrine.

As a visiting judge in the Western District of Tennessee, however, I will not try this case, and the judge who does may resolve this quintessential trial issue differently.

V. ORDER FOR CERTIFICATION

Interpretation of Tennessee law determines the outcome of this case and governs its continued management. Because there is no controlling precedent in the Tennessee Supreme Court that

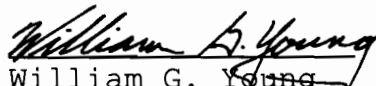
addresses whether Tennessee recognizes any exceptions to the learned intermediary doctrine in failure-to-warn cases involving prescription drugs, this Court respectfully certifies the following questions to the Tennessee Supreme Court pursuant to its Rule 23:

1. Does Tennessee law recognize exceptions to the learned intermediary doctrine when prescription drug companies advertise their products directly to consumers or pay physicians to prescribe their drugs?
2. Does Tennessee follow section 6(d)(2) of the Restatement (Third) of Torts: Products Liability, which mandates that pharmaceutical companies warn patients directly when healthcare providers are poorly positioned to reduce the risk of harm to patients taking prescription drugs?

This Court of course welcomes the advice of the Tennessee Supreme Court on any other questions of Tennessee law deemed material to this case.

The Clerk will transmit these questions and copies of the record, briefs, and appendices in this case to the Tennessee Supreme Court.

IT IS SO ORDERED the 15th day of March 2013.


William G. Young
U.S. District Judge⁴

⁴ Of the District of Massachusetts, sitting by designation.

VI. APPENDIX⁵

A. Contact Information for Petitioner's Counsel:

Counsel for Petitioner: Arnold Anderson (Andy) Vickery, Jim M. Perdue, Jr., and Fred H. Shepherd; Perdue Kidd & Vickery, 510 Bering Dr., Suite 550, Houston, TX 77057-1469; Telephone: 713-526-5939.

Co-Counsel for Petitioner: Edmund J Schmidt III; Law Office of Eddie Schmidt, 1720 West End Ave., Suite 300, Nashville, TN, 37203; Telephone: 615-425-7121.

B. Contact Information for Respondent's Counsel:

Counsel for Respondent: Michael P. Foradas, Renee D. Smith, Andrew P. Bautista; Kirkland & Ellis, LLP, 300 North LaSalle, Chicago, IL 60654; Telephone: 312-862-2000.

⁵ Pursuant to Tennessee Supreme Court Rule 23(3)(D), the name, address, and telephone number of counsel for each party are included in the appendix to this Order. See Tenn. Sup. Ct. R. 23(3)(D).

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